

No. 1:17-md-02775

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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND

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IN RE SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT  
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO ALL BHR-THA AND R3-THA CASES

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DEFENDANT SMITH & NEPHEW, INC.'S MEMORANDUM OF LAW IN SUPPORT OF  
ITS MOTION TO EXCLUDE THE OPINION TESTIMONY OF PLAINTIFFS'  
EXPERT WITNESS MARI TRUMAN

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### **INTRODUCTION AND SUMMARY**

Defendant Smith & Nephew, Inc. (“Smith & Nephew”) respectfully submits this Memorandum in Support of its Motion to Exclude the Testimony of Plaintiffs’ general liability expert witness, Mari Truman, a biomedical engineer. The Court has already excluded some of Ms. Truman’s opinions offered as a general-liability expert in the BHR Track. Memorandum [D.E. 2501] (Mar. 1, 2021) (“BHR *Daubert* Ruling”). Her report in the THA Track is similarly deficient for many of the same reasons. Ms. Truman’s opinions are inadmissible because they are relevant only to preempted claims, are beyond her limited area of expertise, and are not the product of reliable methods. *See* Fed. R. Evid. 702, 401-403. In addition, Ms. Truman’s opinions about what a “reasonable” or “prudent” medical device company should do are inadmissible because they are not pinned to any federal requirements, but amount to nothing more than the *ipse dixit* of the expert.

**First**, many of Ms. Truman’s opinions are relevant only to preempted claims and preempted theories of liability, including those the Court already has held are preempted in its THA preemption ruling. *See In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig.*, 401 F. Supp. 3d 538 (D. Md. 2019) (“*THA Preemption Ruling*”). In particular, Ms. Truman seeks to opine that: (1) use of BHR components as part of a total hip arthroplasty procedure is unreasonably dangerous and a defective design; (2) Smith & Nephew should have changed the labeling of the BHR cup and R3 liner, both of which are under the BHR’s PMA; (3) Smith & Nephew should have withdrawn the BHR cup and R3 liner from the market earlier than it did; and (4) Smith & Nephew did not act as a “reasonable” or “prudent” medical device manufacturer. All of these opinions are expressly preempted because they impose new or different obligations than the obligations FDA has imposed on the BHR. These opinions are inadmissible as they would not “help the trier of fact,” Fed. R. Evid. 702(a), but instead would mislead and confuse the jury and cause unfair prejudice, Fed. R. Evid. 403; *see, e.g., In re Lipitor*

(*Atorvastatin Calcium*) Mktg., Sales Practices & Prods. Liab. Litig., No. 2:14-mn-02502-RMG, 2016 WL 2940778, at \*3 (D.S.C. May 6, 2016) (“Plaintiffs claim[s] that Defendant had a duty to add language to the Warnings section of the [drug] label . . . [are] preempted. Therefore, [the expert’s] testimony to this effect is irrelevant” and “would be confusing and misleading to the jury”).

**Second**, Ms. Truman’s opinions extend well beyond the scope of her qualifications. Ms. Truman is an engineer who is “deferring to the regulatory experts” in this litigation. Deposition of Mari Truman (May 5, 2021) (“Truman THA Track Dep.”) (Ex. A) at 275. She is unqualified to offer regulatory opinions, including those about the scope of Smith & Nephew’s regulatory and legal obligations and whether Smith & Nephew has satisfied those obligations. *See* BHR *Daubert* Ruling at 27 (ruling that Ms. Truman “lacks the regulatory and legal expertise necessary to reliably and helpfully opine so broadly on whether Smith & Nephew conformed its conduct to the requirements of the PMA approval letter and the relevant federal statutes”). Nor, as other courts have held, can she offer opinions about medical causation or other matters outside of the scope of her experience. *See Bayes v. Biomet, Inc.*, No. 4:13-cv-00800-SRC, 2020 WL 5594059, at \*6 (E.D. Mo. Sept. 18, 2020) (excluding Ms. Truman’s medical causation opinions because she “is an engineer, not a medical doctor”); *In re Biomet M2a Magnum Hip Implant Prods. Liab. Litig.*, No. 3:12-MD-2391, 2017 WL 10845178, at \*15 (N.D. Ind. Dec. 21, 2017) (“Ms. Truman can’t testify as an expert on the clinical effects of metal ions”).

**Third**, Ms. Truman may not offer opinions that do not qualify as reliable scientific knowledge within the meaning of Rule 702. She may not offer a factual narrative of documents, or speculate about what Smith & Nephew “knew” or “intended” based upon her review of cherry-picked depositions and documents. These facts, if otherwise admissible, should be presented to the

jury directly rather than filtered through an expert. Nor may she offer legal conclusions that would not assist the trier of fact, but would invade the province of the jury. *See* BHR *Daubert* Ruling at 26-27 (“Truman is not qualified to offer such legal conclusions”). None of these topics qualifies as reliable expert testimony under Rule 702.

## **BACKGROUND**

### **A. Overview of the Relevant Devices.**

There are two FDA-approved or FDA-cleared devices at issue in the THA/R3 Track of this multidistrict litigation: Smith & Nephew’s Birmingham Hip Resurfacing (“BHR”) system and the modular femoral head (“MFH”). Smith & Nephew’s BHR is a premarket approved (“PMA”) orthopedic device indicated for use in hip resurfacing. *See* Expert Report of David L. West, PhD, MPH (Apr. 23, 2021) (“West Report”) (Ex. B) at 61-62, 67-68. The BHR device consists of two components: a metal acetabular cup for fixation to the acetabulum and a metal femoral head resurfacing component for fixation to the femoral head. *See id.* These components of the BHR received premarket approval on May 9, 2006. *See* BHR Premarket Approval Order (May 9, 2006) (“Premarket Approval Order”) (Ex. C). Premarket approval reflects the FDA’s judgment that, based on a multi-volume application and thousands of hours of review, there are reasonable assurances of the device’s safety and effectiveness. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 318 (2008); *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig., BHR*, 300 F. Supp. 3d 732, 745 (D. Md. 2018) (“*In re BHR I*”) (“A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means.”). In connection with its status as a PMA-approved device, the FDA closely monitors and regulates the BHR’s design, marketing, sale, labeling, and indications for use. *In re BHR I*, 300 F. Supp. 3d at 737; *see also* West Report (Ex. B) at 62-64.

In 2008, the FDA approved a line extension of the BHR PMA for a modular acetabular cup, consisting of an R3 acetabular shell and an R3 metal liner. *See* PMA Supplement No. 6 [SN\_BHR\_MDL-0013516] (Ex. D) at 2-7. As part of this PMA supplement, Smith & Nephew added labeling advising surgeons that the R3 metal liner was intended for use with the BHR system only, and that if a surgeon decides to convert from a resurfacing procedure to a total hip procedure (either during a resurfacing or as part of a revision surgery), the R3 metal liner would have to be removed. *See* R3 Modular Resurfacing Acetabular Cups—Surgical Technique Addendum [SN\_BHR\_MDL\_2515991] (Ex. E) at 8, 10.<sup>1</sup>

Upon approval of the line extension, the R3 shell and liner became components of the BHR PMA device. As the Court has ruled, FDA’s pre-market approval extends both to the device as a whole and to each individual component. *See THA Preemption Ruling*, 401 F. Supp. 3d at 551-54. Accordingly, the BHR acetabular cup, metal femoral resurfacing head, the R3 shell, and the R3 metal liner are all—as individual components and as a system—PMA approved by FDA. *See id.* at 552.

The second device at issue in this litigation is the Smith & Nephew modular femoral (hemi) head, or “MFH.” In 2006, Smith & Nephew obtained clearance for the MFH under section 510(k) of the federal Food, Drug & Cosmetic Act (“FDCA”). The MFH is an artificial, cobalt-chrome implant that replaces the natural (or a prior artificial) femoral head. The MFH connects with a femoral stem that is implanted in a patient’s femur. The MFH was cleared for use in hemi-hip arthroplasty, meaning a procedure where an artificial femoral head is implanted to articulate against the patient’s natural acetabulum. West Report (Ex. B) at 67. In countries outside of the

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<sup>1</sup> Smith & Nephew voluntarily recalled the R3 metal liner in 2012. *See* West Report (Ex. B) at 71-72.

United States, the MFH was commercially available for use in total hip arthroplasty, meaning both the MFH and an acetabular cup are implanted. Deposition of Andrew Weymann (*McKanneny v. Smith & Nephew, Inc.*, No. 3:17-cv-00012 (D. Conn.)) (“Weymann Dep.”) (Ex. F) at 35-36.

In the THA and R3 Tracks of this litigation, Plaintiffs allege to have been injured by their physicians’ use of the MFH in combination with a BHR acetabular cup or R3 metal liner as part of a total hip arthroplasty procedure. Specifically, Plaintiffs’ Master Amended Consolidated Complaint for Plaintiffs with BHR Cups, Modular Femoral Heads and Stems (Aug. 14, 2018) [D.E. 878] (“THA MACC”) alleges that Plaintiffs each received a PMA-approved BHR acetabular cup, used in combination with a non-BHR MFH, modular neck sleeve, and femoral stem. THA MACC [D.E. 878] ¶ 116. Plaintiffs’ Master Amended Consolidated Complaint for Plaintiffs with R3 Total Hip Cases (Sept. 21, 2018) [D.E. 966] (“R3 MACC”) alleges Plaintiffs received an R3 metal liner used in combination with an MFH and other non-BHR components as part of a total hip arthroplasty procedure. *See* R3 MACC [D.E. 966] ¶ 10.

These constructs, which Plaintiffs refer to as the BHR-THA and the R3-THA, respectively, *see THA Preemption Ruling*, 401 F. Supp. 3d at 547, were never approved as devices in the United States and Smith & Nephew has never marketed them as such. *See, e.g.*, West Report (Ex. B) at 75, 88-89. Rather, these constructs were chosen by each Plaintiff’s physician as part of his or her practice of medicine. The FDA does not have authority to regulate the practice of medicine, and physicians are able to make their own decisions pertaining to the use of legally marketed medical devices, alone or in combination. *See, e.g.*, 21 U.S.C. § 396. The use of a device by a physician in a manner other than its approved or cleared indication(s) for use is lawful and is referred to as “off-label” use. Indeed, the Supreme Court has explained that “‘off-label’ usage of medical devices (use of a device for some other purpose than that for which it has been approved by FDA) is an

accepted and necessary corollary of FDA’s mission to regulate in this area without directly interfering with the practice of medicine.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001).

A manufacturer is not liable for the physician’s off-label use. Further, responding to questions from physicians or providing components ordered by physicians does not constitute off-label promotion, provided the manufacturer does not suggest or encourage the off-label use or discuss the off-label use without prompting from the physician. *See, e.g.*, West Report (Ex. B) at 59-60. To ensure that manufacturers are not engaged in unsolicited off-label promotion, FDA regularly monitors print and web advertising and investigates credible allegations of off-label promotion. *Id.* at 57-58, 75. If the FDA identifies unlawful off-label promotion by a manufacturer, it can issue a Warning Letter requiring the manufacturer to take corrective action. *Id.* The FDA has never issued Smith & Nephew a warning letter concerning off-label promotion of the BHR, its components, or the MFH. *See* West Report (Ex. B) at 70-75 (“If FDA has found patterns of off-label promotion, the Agency undoubtedly would have issued a Warning Letter.”).

#### **B. The Court’s THA Preemption Ruling.**

On November 9, 2018, Smith & Nephew moved to dismiss Plaintiffs’ THA-Track and R3-Track claims based upon express and implied preemption. [D.E. 1173]. Smith & Nephew highlighted that off-label use by surgeons of BHR components in a “hybrid” system of PMA-approved and 510k-approved components does not insulate Plaintiffs’ claims from federal preemption. Rather, the express preemption provision of the Medical Device Amendments (“MDA”) to the FDCA—Section 360k(a)—draws no distinction between “on-label” and “off-label” uses, and Plaintiffs’ claims impermissibly would impose requirements on BHR components that are in addition to and different from existing PMA requirements. Memorandum [D.E. 1173-1] at 1-2; *see* 21 U.S.C. § 360k(a); *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1343-45 (10th

Cir. 2015) (“§ 360k(a) simply does not contain the distinction . . . between suits addressing on-and off-label uses”).

On August 5, 2019, this Court issued an Order and accompanying Memorandum granting in part and denying in part Smith & Nephew’s Motion to Dismiss. *See* Order [D.E. 1704]; Memorandum [D.E. 1714] (corrected, Aug. 14, 2019). In its Memorandum, the Court recognized that “the BHR cup in the BHR-THA system and the R3 metal liner in the R3-THA system received PMA approval,” but that other components used in those constructs “were approved through the § 510(k) process.” *THA Preemption Ruling*, 401 F. Supp. 3d at 551. Under *Riegel*, PMA-approved devices and components thereof are subject to federal “requirements” relating to safety and effectiveness that preempt non-parallel state law claims, but devices and device components cleared through the § 510(k) process are not subject to such requirements. 552 U.S. at 322-23.

In its *THA Preemption Ruling*, the Court addressed whether “incorporation of a premarket-approved component” with § 510(k) cleared components “extends § 360k(a)’s preemption protection to all claims targeting the device.” 401 F. Supp. 3d at 551-52. Construing the MDA and competing case law on this topic, the Court adopted “a tripartite approach”: “§ 360k(a) preempts non-parallel state-law claims that target pre-market approved components, but it does not govern state-law claims that target a hybrid system’s § 510(k) components or the system as a whole.” *Id.* at 555. Thus, “claims targeting hybrid systems, such as claims directed at the § 510(k) components of the system or claims that do not impose a new requirement on a premarket-approved component would not be preempted.” *Id.* at 554 (citing *Shuker v. Smith & Nephew, PLC*, 885 F. 3d 760, 775 n.15 (3d. Cir 2018)). On the other hand, the Court explained that, if “the BHR cup or the R3 metal

liner [is] ‘at the heart’ of the plaintiffs’ claims” then it “may be that” “preemption will be required.” *Id.* at 556 n.8.<sup>2</sup>

Applying this framework, the Court concluded that the THA-Track and R3-Track Plaintiffs’ claims are preempted to the extent they assert that Smith & Nephew:

- (1) is strictly liable for design defects in or failure to warn regarding the BHR cup or the R3 metal liner, *THA Preemption Ruling*, 401 F. Supp. 3d at 556;
- (2) breached any implied warranty as to the R3 metal liner, *id.*;
- (3) negligently failed to warn “the public or the medical community” about adverse events associated with the BHR cup or R3 metal liner, *id.* at 557-58;
- (4) should have amended the labeling of the BHR cup or R3 metal liner, *id.* at 562;
- (5) should have recalled the BHR cup or R3 metal liner, *id.*; or
- (6) had a duty to train surgeons as to the BHR-THA or R3-THA constructs, *id.* at 563.<sup>3</sup>

**C. Ms. Truman’s Experience and Opinions.**

Plaintiffs have identified Ms. Truman, a biomechanical engineer, as one of their general liability experts. *See* Engineer’s Report (Mar. 19, 2021) (“Truman Report”) (Ex. G) at 1. Ms. Truman offered an expert report on July 15, 2020, in the BHR Track.<sup>4</sup> Both reports are hundreds of pages long, consisting largely of material derived from other expert reports in other litigation,

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<sup>2</sup> The ‘at the heart’ concept comes from *Shuker*, 885 F.3d at 768, which addressed a total hip replacement that involved “multiple” non-PMA components and a Smith & Nephew R3 metal liner. As this Court explained, the court in *Shuker* held that the plaintiffs’ “negligence, strict liability, and breach of implied warranty claims impose[d] requirements on a premarket-approved device,” and were therefore expressly preempted, “because the ‘heart of each of [the Shukers’] claims’ challenged the safety and effectiveness of the R3 metal liner.” *THA Preemption Ruling*, 401 F. Supp. 3d at 554 (quoting *Shuker*, 885 F.3d at 774).

<sup>3</sup> Smith & Nephew moved under 28 U.S.C. § 1292(b) to certify the *THA Preemption Ruling* for interlocutory appeal to the Fourth Circuit. [D.E. 1772]. The Court denied certification on November 27, 2019. *See* Memorandum [D.E. 1951]; Order [D.E. 1952]. Smith & Nephew does not seek to relitigate the prior preemption ruling here, but respectfully reserves the issues presented in its prior motions for further appellate review.

<sup>4</sup> Ms. Truman was also identified as a general liability expert for Plaintiffs in the BHR Track, and gave a deposition on September 25, 2020, about her report relating to the BHR Track.

but her “Findings” section lays out her primary opinions, which are addressed below. *Id.* at 7-13.

Ms. Truman does not hold herself out as a regulatory expert. Truman THA Track Dep. (Ex. A) at 9 (“I’m not offered here in this case as a regulatory expert.”). She states that she has designed implant devices and managed related projects for a number of private-sector companies, Truman Report (Ex. G) at 1-3 (citing curriculum vitae), but acknowledges that she “was not employed in the regulatory department” or in “compliance,” and was “not a quality engineer at any of the organizations that [she] worked for.” Deposition of Mari Truman (Sept. 25, 2020) (“Truman BHR Track Dep.”) (Ex. H) at 36-38. Ms. Truman also concedes that she is neither a medical doctor nor a toxicologist. Truman THA Track Dep. (Ex. A) at 9 (“I’m not a medical doctor, and so I will not be testifying as to medical causation issues.”); Truman BHR Track Dep. (Ex. H) at 54 (“I am not a toxicologist.”).

Multiple courts have excluded Ms. Truman’s opinions on subjects for which she lacks expertise. In *Bayes v. Biomet, Inc.*, 2020 WL 5594059, at \*6, the court excluded Ms. Truman’s opinions regarding medical causation, explaining that “Truman is an engineer, not a medical doctor.” In *Saacks v. Privilege Underwriters Reciprocal Exchange*, No. CV 16-1149, 2017 WL 3867761, at \*2 (E.D. La. Feb. 2, 2017), the court prohibited Ms. Truman from testifying “whether Plaintiff was, or was not injured as a result of the car accident” or “regarding the diagnosis, severity, treatment, or prognosis of Plaintiff’s alleged injuries.” The court further prohibited Ms. Truman from offering an opinion “regarding causation” because she is a “biomechanical expert[]” and such testimony “is better left to the medical doctors.” *Id.*; see also *Hardison v. Biomet, Inc.*, No. 5:19-cv-00069-TES, 2020 WL 4334108, at \*12 (M.D. Ga. July 27, 2020) (“Ms. Truman is not qualified to make medical causation opinions.”). Likewise, in *Ferguson v. Valero Energy Corp.*, No. 06-540, 2009 WL 3335879, at \*1 (E.D. Pa. Apr. 15, 2009), the court excluded Ms. Truman’s

opinions because although “she is being proffered as a biomechanical and a fall expert,” she “opines as if she is being proffered as an oxygen expert and a helmet expert,” and “[s]he is not qualified as either.” The court held that Ms. Truman “may not testify with respect to either topic,” “[n]or may she question the autopsy findings.” *Id.*

Even where Ms. Truman has sought to opine on matters for which she is qualified, courts have excluded her testimony as unreliable. In *Ferguson*, the court excluded Ms. Truman’s testimony with regard to the one area where she was qualified—the mechanics of the fall—as “not reliable.” *Id.* The court explained that Ms. Truman “made no attempt to recreate what happened or to test her hypothesis by creating a computer or other model,” “disavowed her own calculations” when they went against her theory, and otherwise offered “speculative and inconclusory” opinions. *Id.*<sup>5</sup>

In its *Daubert* Ruling in the BHR Track, this Court similarly excluded Ms. Truman’s opinions “that Smith & Nephew’s conduct amounts to a violation of specific statutory requirements” as “stating an improper legal conclusion for which she has no expertise.” BHR *Daubert* Ruling at 26. The Court ruled that “Truman is not qualified to offer such legal conclusions” and that such conclusions are not proper expert testimony in any event because they “would not merely embrace the ultimate issue—they would consume it.” *Id.* at 26-27. It further

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<sup>5</sup> See also *Moore v. Wright Med. Tech., Inc.*, No. 1:14-cv-62, 2016 WL 1316716, at \*7 (S.D. Ga. Mar. 31, 2016) (excluding Ms. Truman’s opinion on device failure rate as not reliable); *Janus v. Wright Med. Tech., Inc.*, No. 1:11-cv-01183, 2013 WL 12241594, at \*9 (C.D. Ill. Aug. 30, 2013) (same); *Kline v. Zimmer Holdings, Inc.*, No. CIV.A. No. 13-513, 2015 WL 4077495, at \*4 (W.D. Pa. July 6, 2015) (rejecting Ms. Truman’s “sham affidavit” that contradicted her deposition testimony regarding design defect), *aff’d*, 662 F. App’x 121 (3d Cir. 2016); *Thompson v. Zimmer Inc.*, No. 11-CV-3099 (PJS/AJB), 2013 WL 5406628, at \*6 (D. Minn. Sept. 25, 2013) (excluding Ms. Truman’s opinions that a device was defective and unreasonably dangerous as “highly questionable,” “lack[ing] the necessary factual support to be admissible,” “not supported by sufficient facts or data,” and “too speculative to be submitted to the jury.”).

found that Ms. Truman “lacks the regulatory and legal expertise necessary to reliably and helpfully opine so broadly on whether Smith & Nephew conformed its conduct to the requirements of the PMA approval letter and the relevant federal statutes.” *Id.* at 27.

Ms. Truman’s Report consists of 361 pages, plus attachments. Truman Report (Ex. G). At her deposition, Ms. Truman stated that the “Executive Summary” on pages 4-13 of her Report, which sets forth extensive “Findings” with multiple subparts, is the “most concise” indication of the opinions that she intends to offer in these cases. Truman THA Track Dep. (Ex. A) at 37-38. She described the remainder of her Report as “the bases for [her] opinions,” but noted that among that material “[t]here will probably be things we discuss” on the witness stand. *Id.* at 38-39.

Ms. Truman’s “Findings” include a number of opinions that are inadmissible. *First*, Ms. Truman has offered opinions that are beyond the limits imposed by the Court in its preemption decision. Specifically, she opines that use of BHR components as part of a total hip arthroplasty procedure is “unreasonably dangerous and defective.” Truman Report (Ex. G) at 7-8. Ms. Truman also seeks to testify that the labeling and instructions for Smith & Nephew’s PMA components were deficient or should have been changed. *E.g., id.* at 13 (the BHR warnings “downplayed the seriousness of the metal pathology risks by placing information about metal sensitivity, metallosis, and inflammatory response in the Potential Adverse Reactions section of the IFU rather than the Warnings section,” which “was misleading”). Ms. Truman further seeks to testify that Smith & Nephew should have recalled its PMA components or contraindicated their use. *See, e.g., id.* at 12 (“[a] responsible manufacture[r] . . . would have withdrawn [these components] from the market earlier than 2012 and 2015”).

*Second*, although she is not a legal or regulatory expert, Ms. Truman seeks to testify about the scope of Smith & Nephew’s regulatory and legal obligations and whether Smith & Nephew

has satisfied those obligations. Specifically, she asserts that Smith & Nephew “failed to warn of the risks of the Birmingham BHR MoM products which were used on label.” *Id.* at 9. She further seeks to testify that “S&N repeatedly failed to comply with Conditions of Approval established in the BHR PMA Approval Letter.” *Id.* at 254-55. She also purports to interpret medical and toxicological data and opine about toxicological and other medical risks, even though she is not a medical doctor or toxicologist.

*Third*, Ms. Truman provides narrative summaries of documents and offers her impressions of their contents. *See, e.g., id.* at 134-76 (Appendix B) (summarizing testimony of S&N personnel); *id.* at 176-79 (Appendix C) (summarizing development of the BHR); *id.* at 191-93 (Appendix F) (summarizing FDA documents). Ms. Truman also seeks to testify about what Smith & Nephew “knew” based upon her review of Smith & Nephew documents.

Each of these opinions is inadmissible for the reasons explained below.

### **LEGAL STANDARD**

Under Rule 702, the federal courts “act as gatekeepers to ‘ensure that any and all scientific testimony . . . is not only relevant, but reliable.’” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 588 (1993)). That gate-keeping responsibility is critically important because, “due to the difficulty of evaluating their testimony, expert witnesses have the potential to ‘be both powerful and quite misleading.’” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) (quoting *Daubert*, 509 U.S. at 595). The Court must “‘make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.’” *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). Rule 702 governs the Court’s gatekeeping responsibility, and dictates that a “witness who is qualified as an expert

by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise” but only “if” four additional conditions are met. Fed. R. Evid. 702.

*First*, the opinion must “help the trier of fact to understand the evidence or to determine a fact in issue.” *Id.*; *Cooper*, 259 F.3d at 199 n.1. As part of its “gate-keeping function,” the Court must determine whether scientific evidence, even if it were reliable, “appl[ies] to the facts in the individual case under consideration.” *Newman v. Motorola, Inc.*, 218 F. Supp. 2d 769, 772 (D. Md. 2002) (citation omitted), *aff’d*, 78 F. App’x 292 (4th Cir. 2003). The question whether such testimony “will help the trier of fact . . . is generally a question of relevance or ‘fit.’” *Id.*; *see also Allen v. Bank of Am., NA*, 933 F. Supp. 2d 716, 734 (D. Md. 2013) (Blake, J.) (excluding expert testimony that would not help the jury determine a fact in issue); *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017) (“Relevant evidence, of course, is evidence that helps ‘the trier of fact to understand the evidence or to determine a fact in issue.’”) (citation omitted). *Second*, the testimony must be “based on sufficient facts or data.” Fed. R. Evid. 702(b); *Cooper*, 259 F.3d at 199 n.1. *Third*, the testimony must be “the product of reliable principles and methods.” Fed. R. Evid. 702(c); *Cooper*, 259 F.3d at 199 n.1. *Fourth*, the court must determine whether “the expert has reliably applied the principles and methods to the facts of the case.” Fed. R. Evid. 702(d); *Cooper*, 259 F.3d at 199 n.1.<sup>6</sup> As to each of these elements, “[t]he proponent of [expert] testimony must establish its admissibility by a preponderance of proof.” *Id.* at 199 (citing *Daubert*, 509 U.S. at 592 n.10).

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<sup>6</sup> Matters that “bear on a judge’s determination of the reliability of an expert’s testimony . . . include: (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.” *Cooper*, 259 F.3d at 199 (citing *Daubert*, 509 U.S. at 592-94).

## ARGUMENT

### **I. MS. TRUMAN’S OPINIONS ABOUT PREEMPTED CLAIMS ARE INADMISSIBLE.**

Ms. Truman’s opinion testimony concerning legal theories preempted by federal law is inadmissible under Rule 702. *See* BHR *Daubert* Ruling at 3-18. Such testimony is not relevant to any claim at issue, and its admission would mislead and confuse the jury, causing unfair prejudice and a waste of both the parties’ and the Court’s time. *See* Fed. R. Evid. 702(a), 403; *Newman*, 218 F. Supp. 2d at 772 (opinions must “apply to the facts in the individual case under consideration”) (citation omitted); *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1150 (D. Minn. 2011) (opinion inadmissible where “it is not relevant to any of [plaintiff’s] claims”); *see also In re Lipitor*, 2016 WL 2940778, at \*3 (ruling that expert’s opinion concerning a preempted claim was “irrelevant” and “would be confusing and misleading to the jury”).<sup>7</sup>

#### **A. Ms. Truman’s Opinions Challenging the Safety of the BHR and R3 Liner Are Inadmissible (Including Finding Nos. 1 & 2).**

Ms. Truman seeks to opine that use of a BHR acetabular cup or R3 metal liner in combination with an MFH as part of a total hip arthroplasty procedure is unreasonably dangerous and a defective design. Truman Report (Ex. G) at 7-8. Her focus is the interaction (or “articulation”) of the acetabular cup and the femoral head. *Id.* at 7 (the design defect is “due to use of the big head metal-on-metal (MoM) articulation”). She opines that this interaction can cause implant failure and the need for revision surgery because “[b]ig femoral head (BFH) MoM

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<sup>7</sup> *See also In re Trasylol Prods. Liab. Litig.*, 763 F. Supp. 2d 1312, 1329-30 (S.D. Fla. 2010) (excluding evidence that defendant failed to provide information to FDA as irrelevant to state-law tort claims because “[s]uch evidence or testimony would instead be relevant to a fraud-on-the-FDA claim that is preempted”); *In re Baycol Prods. Liab. Litig.*, 532 F. Supp. 2d 1029, 1053 (D. Minn. 2007) (excluding expert’s testimony offered “to show that the FDA was misled”); *Bouchard v. Am. Home Prods. Corp.*, 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002) (same).

articulations (>36 mm) have unsafe/high frictional torques, which substantially increases the risk of acetabular cup loosening.” *Id.* She further opines that this interaction can give rise to tissue damage because “MoM articulations generate CoCr wear debris resulting in elevated local or systemic elevated metal ions which are cytotoxic and which elicit immune responses.” *Id.*; *see also id.* at 8 (testifying that MoM articulations are subject to “edge loading,” which “generates higher than expected/excessive wear which results in elevated metal ions with immune response complications (ALTR, ALVAL) and tissue necrosis”).<sup>8</sup>

These opinions are inadmissible because they are relevant only to preempted claims. Opinions targeting the safety of pre-market approved components (even when used off-label by surgeons in a “hybrid” system) impose requirements on the PMA components that are in addition to and different from existing PMA requirements, and are therefore expressly preempted. *THA Preemption Ruling*, 401 F. Supp. 3d at 555 (“§ 360k(a) preempts non-parallel state-law claims that target premarket-approved components”). Indeed, under the Court’s *THA Preemption Ruling*, Ms. Truman’s opinions are inadmissible because BHR components are “at the heart” of her opinions. *See id.* at 556 n.8 (explaining that where “the BHR cup or the R3 metal liner will be ‘at the heart’ of the plaintiffs’ claims” then “it may be” “that preemption will be required”). The BHR components are an essential—“but for”—element of Ms. Truman’s opinions. Specifically, Ms. Truman’s proposed testimony focuses on the interaction of femoral heads with the PMA-approved BHR cup and R3 liner. The BHR components are thus instrumental to Plaintiffs’ claims of injury because the alleged injury does not occur without the BHR components. That is precisely the conclusion that the Third Circuit reached in *Shuker*, where it concluded that “the heart of” the

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<sup>8</sup> Ms. Truman explained that “edge loading” is “where the [acetabular] cup is more introverted and the head is -- instead of riding in the center of -- more -- more towards the center of the dome, it’s riding on the edge of the cup.” Truman THA Track Dep. (Ex. A) at 213.

plaintiffs' negligence, strict liability, and breach of implied warranty claims challenged the safety and effectiveness of the R3 liner because those claims "rest[ed] on the premise that the R3 System was defective only because it was used with the R3 metal liner." 885 F.3d at 774-75 (citation omitted). The same is true here.

Ms. Truman's opinions targeting the safety of the BHR cup and R3 liner therefore run headlong into the Court's holding that "allowing state tort law claims to proceed that would require finding a device unreasonably dangerous would undermine Congress's decision to leave such questions to the FDA." *In re BHR I*, 300 F. Supp. 3d at 743. The Court ruled that "[s]uch products liability laws add to, or are different from, federal regulations and are therefore expressly preempted." *Id.* (dismissing claims). That is because "premarket approval is FDA recognition of a particular medical device's fitness for the market," and "[h]aving received that approval, the BHR system cannot be labeled unreasonably dangerous by state law without imposing requirements on medical devices different from or in addition to federal regulations." *Id.* at 743; *see id.* at 745 ("A manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means."); *id.* at 746 ("Any deviation from the FDA's approved design of the BHR device would violate federal regulations.")).

Accordingly, Ms. Truman's opinions challenging the safety of the BHR cup and R3 liner are inadmissible because they will not "help the trier of fact . . . to determine a fact in issue." Fed. R. Evid. 702(a); *see Newman*, 218 F. Supp. 2d at 772. Ms. Truman's opinions that the BHR cup and R3 liner are "unreasonably dangerous" or "defective" do not "fit" in this litigation because they do not "apply to the facts . . . under consideration." *Id.* (citation omitted). Indeed, admission of Ms. Truman's opinions that the BHR cup and R3 liner are *not* safe would sow confusion and mislead the jury by contradicting FDA's determinations that the BHR and R3 liner (i) are not

“unreasonably dangerous,” and (ii) are “safe” and fit for sale in the United States market. *See In re BHR I*, 300 F. Supp. 3d at 743 (FDA approval is a recognition of a device’s “fitness for the market”); *id.* at 745 (“FDA approval means” that a medical device is “safe”).

Ms. Truman’s opinions challenging the safety of the BHR and R3 liner are inadmissible under Rules 702 and 401 to 403.

**B. Ms. Truman’s Opinions About the Labeling for the BHR Cup and R3 Liner Are Inadmissible (Including Finding Nos. 3-6, 9-11, 13).**

Ms. Truman renders numerous opinions that the labeling for the BHR cup and R3 liner, both of which are under the BHR’s PMA, were deficient or should have been changed.<sup>9</sup> For example, she opines that “[s]urgeons were not aware of the risks of the BHR-THA and R3-THA, because the *labeling for these components* did not discuss the risks of the BHR-THA and R3-THA devices.” Truman Report (Ex. G) at 10 (emphasis added); *id.* at 9 (“S&N failed to warn of the risks of the Birmingham BHR MoM products *which were used on label.*”); *id.* at 10 (“If surgeons used components off-label and looked to the *labeling of the two components*, neither sufficiently warned of the risks of the device as a whole.”); *id.* at 13 (“In the warnings that accompanied the BHR,” Smith & Nephew “downplayed the seriousness of the metal pathology risks by placing information about metal sensitivity, metallosis, and inflammatory response in the Potential Adverse Reactions section of the IFU rather than the Warnings section,” which “was misleading”) (all emphases added). None of these opinions is admissible.

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<sup>9</sup> The BHR’s FDA-approved labeling includes the Instructions for Use or “IFU.” *See Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 931 (5th Cir. 2006) (noting that PMA approval includes “warnings and instructions for physicians contained in the Instructions for Use (‘IFU’)”); *Hill v. Bayer Corp.*, 485 F. Supp. 3d 843, 847 (E.D. Mich. 2020) (“The FDA reviews a device’s proposed labeling, which includes the Instructions for Use (‘IFU’) (for physicians) and Patient Information Booklet (‘PIB’) (for patients), as part of the premarket approval process.”).

In its *THA Preemption Ruling*, this Court held that “§ 360k(a) preempts non-parallel state-law claims that target premarket-approved components.” *THA Preemption Ruling*, 401 F. Supp. 3d at 555. It specifically ruled that “[c]laims alleging that Smith & Nephew was obligated to amend its labeling of the BHR cup and R3 metal liner are expressly preempted by the MDA because they would impose additional, broader requirements on premarket-approved devices.” *Id.* at 562; *see also id.* (“grant[ing] Smith & Nephew’s motion [to dismiss] as to claims alleging that the labeling of pre-market approved components of the hybrid systems was deficient”).

As this Court explained in its BHR Track preemption ruling, where a device such as the BHR or R3 metal liner “receives approval, the manufacturer is forbidden ‘to make, without FDA permission, changes in design specifications, manufacturing processes, *labeling*, or any other attribute, that would affect safety or effectiveness’ unless the manufacturer submits an additional application for FDA review.” *In re BHR I*, 300 F. Supp. 3d at 737 (quoting *Riegel*, 552 U.S. at 319) (emphasis added). Further, the “CBE process – the means by which a medical device manufacturer may change its labeling before seeking FDA approval . . . is discretionary, not mandatory, and thus any state law that would have required Smith & Nephew to change its labeling adds to, or differs from, federal requirements.” *Id.* at 744 n.10. Ms. Truman therefore cannot opine that Smith & Nephew is liable by challenging the content of the BHR or R3 labeling, which FDA has approved, or by arguing that Smith & Nephew had a duty under state law to seek a label change from FDA, which federal law does not require.

Accordingly, Ms. Truman should not be permitted to offer opinions that Smith & Nephew’s labeling for the PMA components was inadequate or that Smith & Nephew should have requested a label change from FDA (or that any label change suggested by Smith & Nephew should have occurred at an earlier date). This testimony is not helpful with respect to any claim that remains in

these cases, *see* Fed. R. Evid. 702(a), but instead would mislead and confuse the jury and cause unfair prejudice to Smith & Nephew, *see* Fed. R. Evid. 403.

**C. Ms. Truman’s Opinions That Smith & Nephew Should Have Recalled the BHR and R3 Liner or Contraindicated Their Use Are Inadmissible (Including Finding Nos. 12 & 13).**

Nor can Ms. Truman testify that Smith & Nephew should have recalled the BHR and R3 liner at any time before they did—2012 for the R3 and 2015 for the BHR (when Smith & Nephew withdrew certain BHR sizes, and contraindicated the use of the BHR in women). According to Ms. Truman, “[a] responsible manufacture[r] . . . would have withdrawn them from the market earlier than 2012 and 2015.” Truman Report (Ex. G) at 12; *see also id.* at 13 (“If Smith & Nephew had acted as a reasonable medical device company and taken appropriate steps for the BHR, then the BHR-THA would not have been available for surgeons.”).<sup>10</sup> These opinions are inadmissible.

In its preemption ruling, this Court ruled that “plaintiffs’ claims that allege Smith & Nephew breached a duty in failing to recall the BHR cup and R3 metal liner are expressly preempted by the MDA, which grants the FDA the authority to withdraw premarket-approval from a device.” *THA Preemption Ruling*, 401 F. Supp. 3d at 562; *see also id.* at 563 (“grant[ing] Smith & Nephew’s motion [to dismiss] as to claims alleging Smith & Nephew breached a duty to recall the BHR cup or the R3 metal liner”). As this Court explained in its BHR Track preemption ruling,

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<sup>10</sup> *See also* Truman Report (Ex. G) at 224 (“At the time that the R3 liner was recalled in 2012 S&N knew that, the BHR revision rate in certain subpopulations were also in the unacceptable range, and higher than the revision rates for the R3 metal liner that they recalled. However S&N failed to recall or stop selling <50 mm diameter BHR, and failed to clearly point out the magnitude of the lower survivorship or greater revision rate in females and in older individuals.”); *id.* at 225 (“Action could and should have been taken to remove the smaller diameter BHR (< 50 mm diameter) from the market and contraindicated use in females in 2009 or 2010, as it eventually was in June of 2015”); *id.* at 262 (“It is likely the FDA and MHRA would have insisted upon further risk mitigation action such as withdrawal of certain head sizes had S&N provided complete information to the FDA[.] This is what eventually happened when MHRA recognized the problem in the UK patients and challenged S&N in 2015.”).

“[t]he FDA may withdraw approval from a device if it determines, based on existing or new information, that ‘such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof.’” *In re BHR I*, 300 F. Supp. 3d at 737 (quoting 21 U.S.C. § 360e(e)(1)(A)-(B)). That is, “[o]nly the FDA has the authority to withdraw approval from a device, and *it did not do so here.*” *Id.* at 737 n.5 (emphasis added). For that reason, the Court has held that claims that Smith & Nephew is liable for failure to recall are preempted by federal law. *See Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 743 n.8 & 747 (D. Md. 2015). Accordingly, Ms. Truman’s opinions are not relevant to any claim that remains in these cases and should be excluded.

Ms. Truman’s opinions also reflect the view that for some period of time prior to the recalls, the BHR (with respect to certain patient sub-populations) and the R3 liner were not fit to be marketed with their FDA-approved labeling because they were unreasonably dangerous. Truman Report (Ex. G) at 8. That claim, too, is untenable in this litigation. After “[h]aving received [premarket] approval, the BHR system cannot be labeled unreasonably dangerous by state law without imposing requirements on medical devices different from or in addition to federal regulations.” *In re BHR I*, 300 F. Supp. 3d at 743 (citing *Riegel*, 552 U.S. at 319). Indeed, “the FDA also has the sole power to declare that a particular device is too dangerous for the market based on new information.” *Id.* (citing 21 U.S.C. § 360e(e)(1)(A)-(B)). Ms. Truman’s opinions that the R3 liner and the BHR (with respect to certain patient subpopulations) should have been recalled prior to 2012 and 2015, respectively, therefore would not help the trier of fact, do not “fit” the circumstances of these cases, and are thus inadmissible. *See Fed. R. Evid.* 702(a). Admission of this testimony would serve only to mislead and confuse the jury and to cause unfair prejudice. *See Fed. R. Evid.* 403.

**D. Ms. Truman’s Opinions Regarding the Duties of a “Reasonable,” “Prudent,” or “Responsible” Manufacturer Are Inadmissible (Including Finding Nos. 11 & 13).**

Ms. Truman likewise cannot testify regarding what actions a “reasonable” or “prudent” manufacturer would take. She renders numerous such opinions throughout her Report. *E.g.*, Truman Report (Ex. G) at 13 (“A reasonable manufacturer is concerned about patient safety and should provide surgeons with both the risks and the benefits of implants in sufficient detail to facilitate a fully informed decision making process.”); *id.* (“If Smith & Nephew had acted as a reasonable medical device company and taken appropriate steps for the BHR, then the BHR-THA would not have been available for surgeons.”); *id.* at 10 (“A responsible manufacturer would have also pointed out that there was a risk for metal pathologies based on historical MoM THA failures and scientific studies.”); *id.* at 13 (“A responsible manufacturer with a ‘commitment to patient safety’ and ‘out of the abundance of precaution’ would have incorporated known risk information and would have provided more warnings to assure optimal patient selection and implant positioning to mitigate risks to patients.”); *id.* at 259 (“I have concluded that S&N violated the standard of care of a reasonably prudent medical device manufacturer in several respects.”).

This Court previously ruled that experts cannot offer opinions regarding purported duties of a reasonable manufacturer that are not based on federal requirements. BHR *Daubert* Ruling at 17 (“To the extent that any expert testimony seeks to rely exclusively on state law duties that are not pinned to federal requirements, they are irrelevant to the remaining claims in this case.”). As discussed below, this Court previously ruled that Ms. Truman is not a federal regulatory expert and cannot testify as to whether Smith & Nephew complied with federal regulations. *Id.* at 26-27. She testified at her deposition that her opinions as to whether Smith & Nephew acted as a reasonably prudent device manufacturer are not tied to federal regulatory requirements. Truman THA Track Dep. (Ex. A) at 12-13; *see also* Deposition of Mari Truman (July 7, 2021) (*Schehrer*

*v. Smith & Nephew, Inc.*) (rough transcript) (Ex. I) at 110-11 (testifying that her opinions about what a reasonable, prudent, or responsible manufacturer would do are *not* based on any “documented source” or “reference manual”).

Because Ms. Truman concedes that her opinions are untethered to any federal requirement, they relate only to preempted allegations, and are not relevant to Plaintiffs’ remaining allegations in this litigation. Indeed, in its earlier preemption ruling in the BHR Track, the Court articulated that its preemption ruling was intended to “exclud[e] claims to the extent the plaintiffs are seeking liability on grounds other than a violation of federal regulations.” *In re BHR I*, 300 F. Supp. 3d at 741; see *also id.* at 740 (Plaintiffs’ state law claims are expressly preempted by federal law where they are not “parallel to a federal regulation”); *id.* at 742 (states may only “impose duties that ‘parallel, rather than add to, federal requirements’” for PMA devices, and “[a] state law is parallel to federal requirements if it seeks to impose liability for conduct that also violates an FDA regulation”). These rulings preempt “any claim”—whatever the alleged source of state law (*e.g.*, negligence, strict liability, etc.)—unless it is “pin[ned]” to conduct that breaches “preexisting federal requirements.” *Id.* at 744; *id.* at 743 n.9 (explaining that “reasoning” underlying dismissal of strict liability claims “applies as well to any other cause of action that might require proof that the BHR device was unreasonably dangerous”).

Thus, Ms. Truman’s opinions that are based on her views of what a “reasonable” or “responsible” manufacturer would do, rather than what federal law requires, are preempted, and inadmissible.

## **II. MS. TRUMAN MAY NOT TESTIFY ABOUT TOPICS OUTSIDE OF HER AREA OF EXPERTISE AS AN ENGINEER.**

Under Rule 702, before a witness can offer opinion testimony, she must be “qualified as an expert by knowledge, skill, experience, training, or education” about the topics of the proposed

testimony. Fed. R. Evid. 702. Accordingly, a witness cannot offer opinion testimony outside of her area of expertise. *See, e.g., In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, 892 F.3d 624, 636-38 (4th Cir. 2018) (affirming exclusion of medical testimony from witness “whose expertise lay in the realm of mathematics rather than medicine”).<sup>11</sup> These principles undermine multiple aspects of Ms. Truman’s core “Findings.” *See, e.g., Truman Report* (Ex. G) at 7-13 (setting forth opinions that FDA-approved labeling was inadequate).

*First*, this Court has ruled that Ms. Truman is not qualified to testify on regulatory matters. BHR *Daubert* Ruling at 26 (“Truman’s conclusion that Smith & Nephew’s conduct amounts to a violation of specific statutory requirements is inadmissible as stating an improper legal conclusion for which she has no expertise.”); *id.* at 27 (Truman “lacks the regulatory and legal expertise necessary to reliably and helpfully opine so broadly on whether Smith & Nephew conformed its conduct to the requirements of the PMA approval letter and the relevant federal statutes”); *id.* at 26-27 (Truman is “not qualified” to offer such opinions). Ms. Truman herself concedes that, in this litigation, she is “not the regulatory expert,” Truman THA Track Dep. (Ex. A) at 99.

Despite this Court’s unequivocal ruling and her own concessions, Truman offers in her Report a multitude of opinions about Smith & Nephew’s regulatory obligations and its compliance with those obligations. For example, as noted, she offers numerous opinions criticizing Smith & Nephew’s labeling of the BHR and R3 liner. Truman Report (Ex. G) at 10 (“Surgeons were not aware of the risks of the BHR-THA and R3-THA, because the labeling for these components did

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<sup>11</sup> *See Giddings v. Bristol-Myers Squibb Co.*, 192 F. Supp. 2d 421, 425 (D. Md. 2002) (expert was “unqualified to state an opinion on product defects” because he “is not a medical doctor,” “pathologist,” or “toxicologist,” and “[b]y his own admission he is not qualified to diagnos[e] medical conditions, provide treatment, or [give a] prognosis for a patient”); *see also Dura Auto. Sys., Inc. v. CTS Corp.*, 285 F.3d 609, 612-14 (7th Cir. 2002) (“A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty.”).

not discuss the risks of the BHR-THA and R3-THA devices.”); *id.* (“If surgeons used components off-label and looked to the labeling of the two components, neither sufficiently warned of the risks of the device as a whole.”); *id.* at 13 (numerous criticisms of the BHR label). Ms. Truman also opines that Smith & Nephew did not comply with standards promulgated by the International Organization for Standardization. *Id.* at 10 (“S&N was not compliant with the spirit of ISO EN 13485, ISO14971 (2007, 2012), and ISO 9001 (2000) as evidenced by deficiencies in risk assessment, risk mitigation activities and performance testing.”). Ms. Truman’s Report also includes a lengthy appendix in which she opines that Smith & Nephew failed to comply with the conditions of approval in the BHR’s PMA approval letter. *Id.* at 238-58 (Appendix K-Analysis, PMA Reporting Violations).<sup>12</sup>

The substance of Ms. Truman’s opinions underscores her lack of expertise, as she repeatedly misconstrues the requirements of the Medical Device Act. For example, this Court has held that Smith & Nephew was not required by federal law to modify its FDA-approved labeling because the FDA’s CBE process “is discretionary, not mandatory, and thus any state law that would have required Smith & Nephew to change its labeling adds to, or differs from, federal requirements” and is “expressly preempted.” *In re BHR I*, 300 F. Supp. 3d at 744 n.10. In contrast, Ms. Truman seeks to tell the jury that Smith & Nephew should be held liable for failing to update the labeling of the FDA-approved components. Truman Report (Ex. G) at 13 (“S&N should have put the metal ion and metal pathology information and risks in the Warning section, and they should have more fully defined the metal pathologies.”). Pursuant to this Court’s prior ruling, Ms. Truman’s testimony regarding federal regulatory obligations and compliance with those

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<sup>12</sup> At her deposition, Ms. Truman testified that her discussion in Appendix K was a vestige of her BHR Track Report and “doesn’t directly affect” her opinions in the THA Track cases. Truman THA Track Dep. (Ex. A) at 86-87. This discussion nevertheless remains in her Report.

obligations is beyond the scope of her expertise and inadmissible under Rule 702. These opinions should be excluded.

*Second*, Ms. Truman concedes that she is neither a toxicologist nor a medical doctor. Truman THA Track Dep. (Ex. A) at 9 (“I’m not a medical doctor, and so I will not be testifying as to medical causation issues.”); *id.* at 96 (same); Truman BHR Track Dep. (Ex. H) at 54 (“I am not a toxicologist.”). Nevertheless, in her Report, she purports to interpret medical and toxicological data and expound upon the magnitude and nature of toxicological and other medical risks.<sup>13</sup> *See, e.g.*, Truman Report (Ex. G) at 10 (“While it was advertised that the metal-on-metal implant would not wear through or wear away, there was no mention that there were millions more bioreactive particles that could become toxic or induce toxicity to tissues”).<sup>14</sup> Ms. Truman’s education, training and experience as an engineer do not qualify her to offer these opinions, as other courts previously have concluded. *See In re Biomet*, 2017 WL 10845178, at \*15 (holding that “Ms. Truman can’t testify as an expert on the clinical effects of metal ions”); *Hardison*, 2020 WL 4334108, at \*12 (“Ms. Truman cannot provide medical causation opinions, including that the design defect contributed to Mr. Hardison’s death, injuries, and need for revision surgery.”). As

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<sup>13</sup> In its *Daubert* Ruling in the BHR Track, this Court ruled that “to the extent that Truman’s opinion that the BHR system contained bioreactive particles that could become toxic to tissues is based upon the testimony of experts qualified to express that opinion, her opinion will not be excluded.” BHR *Daubert* Ruling at 21. Smith & Nephew acknowledges this ruling, but raises the argument to preserve it for further review.

<sup>14</sup> *See also* Truman Report (Ex. G) at 3 (stating that the “purpose of [her] investigation” was “to determine if the S&N BHR-THA and R3-THA hip devices were unreasonably dangerous and defective in a manner that *caused* failures including diagnosed injuries such as soft tissue inflammatory injury, synovial hypertrophy, fluid collections (pseudotumor), soft tissue destruction/necrosis (e.g. abductor damage and instability/dislocations), bone osteolysis/cysts, elevated serum metal ions, loosening and/or and recurrent disabling groin or leg pain, leading to revision total hip surgery to correct and often resulted in residual pain and functional deficits”) (emphasis added).

was the case in *Hardison*, “[t]o the extent Ms. Truman reiterates medical professionals’ opinions in her report, medical experts would more appropriately establish those opinions.” *Id.*

### **III. MS. TRUMAN OFFERS OPINIONS THAT ARE NOT BASED UPON A RELIABLE METHODOLOGY AND ARE THEREFORE INADMISSIBLE.**

Ms. Truman’s opinions also are inadmissible because they are not based upon a reliable scientific methodology. *See Cooper*, 259 F.3d at 203 (citing *Kumho Tire Co.*, 526 U.S. at 157). Under Fourth Circuit law, trial courts must exercise their gatekeeping function to make certain that an expert “‘employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.’” *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152). That gate-keeping responsibility is necessary because, “due to the difficulty of evaluating their testimony, expert witnesses have the potential to ‘be both powerful and quite misleading.’” *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 595). Ms. Truman’s opinions fall short of these standards.

#### **A. Ms. Truman’s Factual Narratives, Summaries of Smith & Nephew Documents, and Speculation as to What Smith & Nephew “Knew” Are Not Proper Subjects of Expert Testimony (Including Finding Nos. 4 & 12).**

Ms. Truman may not act as a “human highlighter” who provides summaries of documents and offers her impressions of their contents to the jury. *See, e.g.*, Truman Report (Ex. G) at 134-76 (Appendix B) (summarizing testimony of S&N personnel); *id.* at 176-79 (Appendix C) (summarizing development of the BHR); *id.* at 191-93 (Appendix F) (summarizing FDA documents).<sup>15</sup> An expert cannot provide a factual narrative that merely summarizes documents.

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<sup>15</sup> In its *Daubert* Ruling in the BHR Track, this Court reserved ruling on whether Ms. Truman’s appendix in her BHR Track Report summarizing the development of the BHR is admissible. BHR *Daubert* Ruling at 24-25. The Court observed that this summary is “not obviously related to any of her conclusions or findings,” and reserved ruling because “it is difficult to determine whether such a summary will be offered solely for the purpose of constructing a factual narrative or for some purpose that calls for an expert’s specialized knowledge.” *Id.* Smith & Nephew raises this

Expert testimony requires “specialized knowledge.” Fed. R. Evid. 702(a). A narrative summarizing documents, by contrast, invades the province of the jury, amounts to mere advocacy on a plaintiff’s behalf, and thus falls outside the scope of what Rule 702 permits. *See In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1337 (S.D. Fla. 2010) (holding that expert’s opinions are improper because they “consist of a narrative of selected regulatory events and a summary of [defendant’s] internal documents”).<sup>16</sup> As explained in the *Rezulin MDL*, an expert’s narrative is inadmissible because it “does no more than counsel for plaintiff will do in argument, i.e., propound a particular interpretation of [defendant’s] conduct.” *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 551 (S.D.N.Y. 2004) (citation omitted). Ms. Truman may not “merely read, selectively quote from or ‘regurgitate’ the evidence.” *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 191-92 (S.D.N.Y. 2009).

Ms. Truman likewise should not be permitted to offer opinions as to what Smith & Nephew “knew” based upon her review of Smith & Nephew documents.<sup>17</sup> Her opinions about Smith & Nephew’s “intent, motives or states of mind”—derived from a review of documents and

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issue to preserve it for further review. This Court’s prior ruling did not address other document and deposition summaries in Ms. Truman’s THA Track Report.

<sup>16</sup> *See also In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008) (noting that documents are “just as easily summarized by a jury”), *aff’d in relevant part, rev’d in part on other grounds*, 586 F.3d 547 (8th Cir. 2009); *Bouchard*, 213 F. Supp. 2d at 809 (excluding expert’s “personal belief as to the weight of the evidence”); *In re Air Crash Disaster at New Orleans, La.*, 795 F.2d 1230, 1233 (5th Cir. 1986) (“[T]he trial judge ought to insist that a proffered expert bring to the jury more than the lawyers can offer in argument”); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (if “such evidence is admissible, it should be presented to the jury directly”).

<sup>17</sup> *See, e.g.*, Truman Report (Ex. G) at 3 (“S&N knew that many surgeons in the USA utilized a BHR-THA or an R3-THA, and that this use was an [sic] off label”); *id.* at 9 (“Based on my review of S&N documents, S&N knew of the dangerous adverse reactions and later unacceptable revision rates in S&N BHR-THA and R3-THA and BHR resurfacing patient sub-populations in the 2006-2011 time frame.”); *id.* at 12 (“By 2011, S&N knew of performance problems with BHR-THA and R3-THA, both involving use of the BHR-MFH.”); *id.* at 28 (“S&N knew or should have known of the off-label use”).

depositions—are inadmissible because they have “no basis in any relevant body of knowledge or expertise.” *In re Rezulin*, 309 F. Supp. 2d at 546; *see also DePaepe v. Gen. Motors Corp.*, 141 F.3d 715, 720 (7th Cir. 1998) (excluding expert’s opinion about defendant’s motive or purpose); *In re Fosamax*, 645 F. Supp. 2d at 192 (excluding “conjecture” regarding the “knowledge, motivations, intent, state of mind, or purposes” of pharmaceuticals manufacturer).

Nor may Ms. Truman speculate about how the FDA or physicians (specifically or generally) would have reacted in response to different information. Truman Report (Ex. G) at 262 (“It is likely the FDA and MHRA would have insisted upon further risk mitigation action such as withdrawal of certain head sizes had S&N provided complete information to the FDA.”); *id.* at 11 (“S&N’s promotion of BHR metallurgical benefits without full disclosure of risks led surgeons to select this procedure.”); *id.* at 130 (“If they had been warned of the risks of elevated metal ions and associated ALTR with the BHR devices, surgeons may have recognized and treated failing MoM devices sooner, sparing patients additional pain, suffering, and functional loss.”). In addition to her lack of qualifications to make these predictions about FDA and physicians, Ms. Truman may not opine as to the state of mind of FDA officials, physicians and patients because “surmising as to what [they] would do with different information is purely speculative and not based on scientific knowledge.” *In re Diet Drugs Prods. Liab. Litig.*, No. MDL 1203, 2001 WL 454586, at \*18 (E.D. Pa. Feb 1, 2001); *see also Tyger Constr. Co. v. Pensacola Constr. Co.*, 29 F.3d 137, 142 (4th Cir. 1994) (“An expert’s opinion should be excluded when it is based on assumptions which are speculative and are not supported by the record.”); *Cooper*, 259 F.3d at 203 (excluding expert testimony that constitutes “little more than speculation”); *In re Rezulin*, 309 F. Supp. 2d at 556-57 (concluding that it is “speculative” “as to whether physicians would have prescribed [a drug] if different information about [the drug] had been available”).

Finally, all of these opinions are inadmissible for the additional reason that Ms. Truman had no role in selecting the documents and depositions that she reviewed for the formulation of her opinions in these cases. Truman THA Track Dep. (Ex. A) at 55 (“Q. And who chose what documents would be necessary for you to review in the formation of your opinions in the report? Who chose these documents here? A. I was provided them by -- by my client.”). Although Ms. Truman’s Report states that she has “had access to the documents electronically produced by S&N in this litigation,” Truman Report (Ex. G) at 4, she admitted at her deposition that she did not select the materials that she reviewed and did not know how those materials were selected. Truman THA Track Dep. (Ex. A) at 56 (“I don’t know how it was selected, but this is what I was given.”); *see also id.* at 253 (testifying that the Smith & Nephew documents she reviewed “were limited to the documents that were given to [her] by the lawyers”). The Fourth Circuit has made clear that “cherry-picking” of information “does not reflect scientific knowledge, is not derived by the scientific method, and is not ‘good science.’” *In re Lipitor*, 892 F.3d at 634 (citation omitted) (“[r]esult-driven analysis, or cherry-picking, . . . is a quintessential example of applying methodologies . . . in an unreliable fashion”).

**B. Ms. Truman’s Legal Conclusions Are Improper and Inadmissible (Including Finding Nos. 1-2, 3-6, 9-11, 13).**

This Court also has ruled that Ms. Truman may not offer legal conclusions, finding that such opinions “would not merely embrace the ultimate issue—they would consume it.” BHR *Daubert* Ruling at 26-27. Expert opinions that merely recite “‘a legal standard or draw[] a legal conclusion by applying law to the facts [are] generally inadmissible.’” *United States v. McIver*, 470 F.3d 550, 561-62 (4th Cir. 2006). An expert’s testimony is an impermissible legal conclusion when “‘the terms used by the witness have a separate, distinct and specialized meaning in the law different from that in the vernacular.’” *JFJ Toys, Inc. v. Sears Holdings Corp.*, 237 F. Supp. 3d

311, 324 (D. Md. 2017) (citation omitted). An expert may not “take away from the jury its responsibility to determine the facts and, ultimately, whether the defendants are liable.” *Sprint Nextel Corp. v. Simple Cell, Inc.*, No. CCB-13-617, 2016 WL 524279, at \*5 (D. Md. Feb. 10, 2016) (Blake, J.) (excluding portions of “report that are unhelpful legal conclusions”).

Here, Ms. Truman’s Report is replete with impermissible legal conclusions. For example, Ms. Truman states that BHR-THA and R3-THA hip devices are “unreasonably dangerous and defective,” Truman Report (Ex. G) at 8; that Smith & Nephew “failed to warn its customers in a timely manner of the unreasonable dangers posed” by BHR-THA or R3-THA devices, *id.* at 11; and that Smith & Nephew failed to act as a reasonable medical device manufacturer, *e.g.*, *id.* at 13 (“If Smith & Nephew had acted as a reasonable medical device company and taken appropriate steps for the BHR, then the BHR-THA would not have been available for surgeons.”). And, according to her, “[t]he BHR is misbranded under the federal statute and all parallel state misbranding statutes,” for multiple reasons. *Id.* at 258.<sup>18</sup>

These opinions are inadmissible legal conclusions. Ms. Truman’s “use of terms with considerable legal baggage” are improper legal opinions that “invade[] the province of the jury.” *United States v. Perkins*, 470 F.3d 150, 158 (4th Cir. 2006). She may not offer legal conclusions “reserved for the fact-finder.” *JFJ Toys*, 237 F. Supp. 3d at 325; *see also Moore*, 2016 WL 1316716, at \*9 (excluding Ms. Truman’s opinions that reflected inadmissible legal conclusions).

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<sup>18</sup> *See also* Truman Report (Ex. G) at 259-65 (Appendix L-Violations of the Standard of Care), which discusses Ms. Truman’s “conclu[sion] that S&N violated the standard of care of a reasonably prudent medical device manufacturer in several respects,” *id.* at 259; *id.* at 254-55 (“S&N repeatedly failed to comply with Conditions of Approval established in the BHR PMA Approval Letter.”).

**CONCLUSION**

For these reasons, the opinions offered by Ms. Truman are inappropriate expert testimony and are inadmissible under Federal Rules of Evidence 702 and 401-403.

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**CERTIFICATE OF SERVICE**

I, Paul J. Zidlicky, hereby certify that on this 13th day of July, 2021, I electronically filed the foregoing with the Court using the CM/ECF system, and thereby delivered the foregoing by electronic means to all counsel of record.

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